CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number:83-232

Trade Name: Hydrochlorothiazide Tablets 50mg

Generic Name: Hydrochlorothiazide Tablets 50mg

Sponsor: Danburry Pharmacal Inc.

Approval Date: 1/24/75

INDICATION(s): Adjunctive therapy in edema associated with congestive heart failure, hepatic cirrhosis, and corticosteroid and estrogen therapy.

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APPLICATION: 83232

CONTENTS

	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
Tenative Approval Letter				X
Approvable Letter				X
Printed Labeling	X			
Medical Review(s)	X			
Chemistry Review(s)	X			
EA/FONSI				X
Pharmacology Review(s)				X
Statistical Review(s)				
Microbiology Review(s)				X
Clinical Pharmacology Biopharmaceutics Review(s)				X
Bioequivalence Review(s)	X			
Administrative/ Correspondence Document(s)	X			

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Application Number: 83232

APPROVAL LETTER

NDA 83-232

AF 42-129

Danbury Pharmacal, Inc.
Attention: Mr. Ira Sacks
131 West Street
Danbury, CT 06810

JAN 24 1975

Gentlemen:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Hydrochlorothiazide Tablets, 50 mg.

Reference is also made to your communication dated November 12, 1974, amending the application.

We have completed the review of this abbreviated new drug application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved.

Any significant change in the conditions outlined in this abbreviated new drug application requires an approved supplemental application before the change may be made, except for changes made in conformance with other provisions of section 314.8 of the new drug regulations.

This Administration should be advised of any change in the marketing status of this drug.

The enclosures summarize the conditions relating to the approval of this application.

That part of your submission pertaining to an alternate supplier of the active ingredient is being handled in a separate communication.

Sincerely yours,

/S/

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

Drug Application

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